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#19

Louis E. Davidson
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P.O. Box 40
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RE: Patent Term Extension
Application for
U.S. Patent No. 4,406,906
Issued: September 27, 1983

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,406,906, issued September 27, 1983, is eligible for patent term extension under 35 USC 156. The period for extension has been determined to be two (2) years.

The period of extension has been calculated using the FDA determination of the length of the regulatory review period published in the Federal Register on April 12, 1989 as follows:

$$\begin{aligned}\text{Period} &= 1/2 \text{ (Testing Phase)} + \text{Approval Phase} \\ &= 1/2 (0) + (1921) \\ &= 1921 \text{ days}\end{aligned}$$

Since the regulatory review period began (September 6, 1979) before the patent issued (September 27, 1983), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the determination of the length of the extension period. 35 USC 156(c) (From September 6, 1979 to September 27, 1983 is 1482 days; this period is subtracted from the number of days occurring in the testing phase and the approval phase according to the FDA determination of the length of the regulatory review period. No determination of a lack of due diligence was made. The exception of 35 USC 156(c)(3) does not operate to reduce the period determined above. The limitation of 35 USC 156(g)(6)(C) applies in the present situation because Patent No. 4,406,906 was issued (September 27, 1983) before the date of enactment (September 24, 1984) of 35 USC 156; the date of exemption under Section 505(i) of the Federal Food, Drug and Cosmetic Act involving Nimotop became effective (September 6, 1979), was before the date of enactment, and the product was not approved for commercial marketing or use

(December 28, 1988) before the date of enactment. Since the period of extension calculated under 35 USC 156(c) for Patent No. 4,406,906 and Nimotop cannot exceed two (2) years under 35 USC 156(g)(6)(C), the period of extension will be for two (2) years.

A single request for reconsideration of this final determination as to eligibility and the length of extension of the term of U.S. Patent 4,406,906 may be made if filed within one (1) month of the date of this notice. This period is not subject to an extension of time under 37 CFR 1.136(a). In the absence of such request, the Commissioner will issue to the applicant for extension of the term of Patent No. 4,406,906, a certificate of extension, under seal, for a period of two (2) years. The rights derived from the patent during the period during which the patent is extended are defined in 35 USC 156(b). Upon issuance of the certificate of extension the following information will be published in the Official Gazette:

U.S. Patent No. 4,406,906, granted
September 27, 1983 to Horst Meyer et al
Owner of Record: Bayer Aktiengesellschaft
Title: CEREBRAL THERAPEUTIC AGENT AND ITS USE
Classification: 514-356
Product Trade Name: Nimotop
Term Extended: 2 years

C.E. Van Horn

Charles E. Van Horn
Patent & Trademark Office

cc: Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

RE: Nimotop
FDA Docket # 89E-0104